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UNITED STATES DISTRICT COURT

Northern District of California

CYNTHIA GUTIERREZ, JOSE HUERTA, SMH, RH AND AH, Plaintiffs, vs. SANTA ROSA MEMORIAL HOSPITAL, ST. JOSEPH HEALTH AND DOES 1-50, inclusive, Defendants.	Case No.: 3:16-cv-02645-SI DECLARATION OF MICHAEL ARRIGO IN SUPPORT OF PLAINTIFFS' SUPPLEMENTAL BRIEF IN SUPPORT OF FIRST DISCOVERY LETTER BRIEF "Telephonic Appearance" Honorable Susan Illston Pre-Trial Conf: November 6, 2018 Trial Date: November 9, 2018

DECLARATION OF MICHAEL ARRIGO IN SUPPORT OF PLAINTIFFS' SUPPLEMENTAL BRIEF IN SUPPORT OF FIRST DISCOVERY LETTER BRIEF
3:16cv02645-SI

Introduction

Counsel requested that I provide supplemental information responsive to the July 10, 2018 Court Order requesting that the Parties in this matter submit a supplemental briefing regarding "**what benefit or burden, if any, production of the EHR will provide.**" My Curriculum Vitae was included as **EXHIBIT A** in my prior Declaration.

Respectfully, the Defendant has attempted to mischaracterize duplicate records or "merging" of Records [1] advocating for it as a customary practice [2] rather than acknowledging it as an **error**. SRMH's own E.H.R. vendor Meditech describes duplicate records as an "error" in its training materials which may be caused by '…miscommunication…,' 'scheduler error,' 'admissions errors." [3] [4] I am not seeking to create an undue burden to a hospital with a mirror image of the Defendant's entire system, merely the opportunity to inspect and copy the data associated with **one** patient, the Plaintiff Ms. Gutierrez. Once I am provided with E.H.R. access, the time required to find Ms. Gutierrez record should take minutes, if the system is properly configured.

I am requesting electronic and on-site access for a **less than an 8-hour day** to Defendant's E.H.R. This does not create an unreasonable burden to the Defendant. I am merely requesting information that SRMH is **required to maintain** under HIPAA and the HITECH Act. I estimate the burden to SRMH in cost and time to be one the provision of an individual with specialized E.H.R. knowledge and skill in the Defendant's existing workforce, for less than an 8-hour day.

I request to verify whether duplicated records contain conflicting contemporaneous information about the treatment of patient Gutierrez before during and after her adverse drug reaction ("code"), and whether conflicts exist with respect to prior statements by Defendant, or between multiple, duplicated copies of the Plaintiff's information in the E.H.R.

Definition of Duplicate Merged or Overlay Medical Records

Duplicate medical records and overlays are created as a result of patient identification errors. A duplicate medical record occurs when a single patient is associated with more than one medical record, or when more than one medical record exists with inconsistent information about the patient. Oftentimes, duplicate medical records are partial duplicates that only capture a portion of a patient's medical history. An overlay occurs when one patient's record is overwritten with data from another patient record, creating a combined, inaccurate record. [5] I have examined the limited audit logs produced in this case and it is clear there are duplicated and merged records. Defendant does not deny the duplication or merging in their letter to the Court on June 28, 2018.

Duplicate Medical Records and Overlays are Critical Issues

According to published documents by the American Medical Informatics Association, "Patient matching problems pose significant dangers for patients because, if patients are treated based on incomplete or inaccurate knowledge about their medical history or profile, serious errors and complications can ensue. For example, a duplicate medical record may not include the correct information about a patient's blood type, allergies, or their diagnostic, medication, or family histories. Similarly, overlays include inaccurate information about patients' medical histories because they merge information from separate individuals into a single patient record. **The imprecision of these medical records can cause unnecessary and costly duplicate testing, ineffective treatments, unintended medication interactions, and inappropriate care that can harm patients**. Duplicate medical records can also negatively impact communications between healthcare providers and their patients: duplicate medical records are associated with a higher risk of missing important laboratory results and a higher likelihood that patients are subjected to unnecessary testing." [6]

Relevance of Meaningful Use and ARRA HITECH Act of 2009 in this Case

In a meeting and conference that I attended telephonically between Plaintiff and Defendant's counsel, Defendant stated that SRMH compliance with Meaningful Use in the

context of this case "doesn't matter." I respectfully disagree. The HITECH Act and Meaningful Use were designed in part as a method to provide an electronic record system to prevent medical errors and ensure patient safety.

In 1999, the National Academies of Sciences Engineering and Medicine stated, "Health care in the United States is not as safe as it should be--and can be. At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented, according to estimates from two major studies. Even using the lower estimate, preventable medical errors in hospitals exceed attributable deaths to such feared threats as motor-vehicle wrecks, breast cancer, and AIDS."[7] In 1999 when this article was published, American Medicine operated in a paper-based world and continued to do so for over another decade until the ARRA HITECH ACT of 2009. [8]

Without universal electronic access to the patient's clinical history, physicians made less informed decisions about the patient's care. [9] As the National Academies of Science article concludes, "More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them." [10] One of the aims of the work discussed in 1999 was "Developing and testing new technologies to reduce medical errors." [11]

Ten years later, the HITECH Act of 2009 [12] [13] allocated $19.2 billion toward the development of Healthcare IT. It provided the U.S. Department of Health and Human Services (HHS) the authority to establish programs to improve health care quality, safety and efficiency through the promotion of health IT, including electronic health records and private secure health information exchange.[14] Many of the mandates for the HITECH Act that are relevant to this case, and in my opinion are set forth in **EXHIBIT B** of my prior Declaration.

The HITECH Act's key message to health care providers was this: We will use taxpayer dollars to modernize our nation's health infrastructure; and if you demonstrate you are a meaningful user of an E.H.R., HHS will reimburse you for some of your technology adoption costs and then incentivize you for reporting data that indicates improved quality of care. [15]

Multiple federal agencies that participated in directing health care's migration from paper to electronic health records to provide standards, data and technology that could be uniformly accessible included but were not limited to:

- The U.S. HHS Centers for Medicare and Medicaid Services (CMS) wanted to improve patient safety while combatting fraud. [16] [17]
- The U.S. Centers for Disease Control and Prevention ("CDC") wanted better reporting of infectious diseases for population health safety and risk mitigation[18]
- The National Council for Prescription Drug Programs (NCPDP) established national prescribing standards to improve patient safety in emergencies. [19]
- The U.S. Substance Abuse and Mental Health Services Administration (SAMSHA) substance abuse health information confidentiality protections regarding electronic data in compliance with 42 CFR Part 2.[20]
- The Regenstrief Institute [21] partnered with HHS to provide LOINC codes so that lab orders and results could be electronically delivered directly to the ordering provider, reducing time and avoiding re-keying of paper-based information for improved accuracy, timely care and patient safety.

The Office of the National Coordinator (ONC), an HHS sub agency, collaborated with stakeholders and EHR vendors to develop required clinical and functional elements that the software **must** demonstrate it can perform, including but not limited to: (a) structured data, and (b) clinical decision support tools to help overworked and distracted physicians and reduce medical errors.

Structured data fields prevent data entry except numbers or letters specific to that field. For example, structured data would be the patient's date of birth, social security number if available, telephone number or an adverse reaction to a drug as it is chosen from a drop-down menu. Structured data also is a lab result, or an ICD-10 code used to identify specifics about the patient's diagnosis. Prescriptions and dosages also fall into the structured data field. [22]

Clinical Decision Support [23] features search the patient's chart for allergies or adverse drug reactions and alerts the provider if the wrong medication is ordered or if it is administered as an injection when it should have been an oral medication. It also may quickly search a database for new treatment options.

These two capabilities among others enable an E.H.R. to send warning alerts if the patient is allergic or had an adverse reaction to a drug.

E.H.R.s also include narrative fields. For example, a physician may write out an educational plan or make notes about the patient's family caregiver. But a physician who also is a meaningful user of health technology would not write out a prescription in a non-searchable field because it would get lost in the data fields and would not be sent to the pharmacy.

The transition to an E.H.R. also requires cultural and behavioral changes. When purchasing and implementing an E.H.R., hospitals establish clinical policies and procedures so that each authorized user understands how to enter data consistently into the system. One of the most commonly used policies is "wait for the EHR to check for an existing patient record before creating a new or duplicate record."[24]

Duplicate records are a patient safety risk as some critical information lives in one or the other and not immediately available to the physician for decision making. Certified E.H.R.s require that patient searches be conducted by name, date of birth, or patient record number.

Another clinical policy is to direct one clinician, for example the attending physician, to immediately acknowledge any "panic value" or high-risk lab results before importing the results into the patient chart. [25]

To claim to be a meaningful user, data may only be collected from structured fields.

Burden to SRMH and Benefit to Plaintiff

1. Santa Rosa Memorial Hospital (SRMH) attested under the HITECH Act that it was a meaningful user of an E.H.R, entitling it to receive $5,063,846 federal incentive funds over five years. SRMH received most of those funds ($4,571,491) between February 7, 2012 to November 19, 2014. [26] SRMH is part of the Providence St Joseph Health System with 51 hospitals[27], each of which was could attest to Meaningful Use and receive similar stimulus funds subject to the size and discharge data for each hospital not only from Medicare but from the State Medicaid where the hospital is located.[28]

2. To receive over $5 million, SRMH had to attest truthfully that its acquisition and installation of the E.H.R.'s capabilities, as well as the hospital's policies and procedures complied with the HITECH Act or risk liability under the False Claims Act. [29] [30] Attesting HIPAA Covered

Entities must keep these documents on file for at least six (6) years.[31] Therefore, SRMH should have its 2014 attestation data available until 2020 for inspection. Based on my experience with the U.S. Department of Justice in Qui Tam False Claims Act investigations regarding E.H.R.'s, any attesting hospital can be subjected to Federal audits of their systems that would be more comprehensive than what I recommended to Plaintiff's counsel.

3. I am merely requesting to inspect what SRMH is **required** to provide, therefore there should be no unreasonable burden.
    a. Once I am provided with a login to the E.H.R., for example, initial access to the patient's chart might take one to two minutes.
    b. Inspecting multiple copies of the charts, receiving documents that SRMH is required to have should take less than one 8-hour day.
    c. In my opinion it would be appropriate for SRMH to create a temporary user name and password to access the E.H.R. and related modules before I arrive, and to allocate one SRMH employee to escort me during my work for the day.
    d. I wish to clarify to the Court that Plaintiff is not requesting a 'mirror image' of the entire E.H.R. database for all patients, but simply an opportunity to view and copy those records pertaining to the Plaintiff to determine their veracity.
    e. Several of the required provisions of the HITECH Act were delineated in my prior Declaration.

4. The Defendants in this case have erroneously asserted that an expert in E.H.R. systems would know that creating blank, duplicate records is common practice. I respectfully disagree. My experience as an expert for the DOJ prosecuting fraud based on incorrect statements about data integrity in E.H.R.s indicates that exactly the opposite is true. I consulted with two physicians on my team as well as a Meditech E.H.R. programmer and a former advisor to the U.S. Government on implementations of E.H.R.s on my team. No one except the Defendant can find any valid clinical or technical reason for creating a duplicate, blank record for Ms. Gutierrez, even in an emergency "code" situation.

5. As stated in my prior Declaration with citations, duplicate records create patient safety issues. Duplicate record of medication reconciliation and management creates the possibility of errors.

6. Meditech, SRMH's own E.H.R. vendor also reiterates that duplicated records are **errors.**

7. The Defendant asserts that by stating that duplicated records of Ms. Gutierrez are errors, that I am calling the integrity of the hospital into question. Santa Rosa Memorial Hospital and the St. Joseph's health system presided over one of the largest HIPAA breaches of health information in the history of hospitals in the U.S. with over 33,000 patient records breached (see St. Joseph Health to pay $7.5M settlement to patients affected by 2012 data breach, dated March 15, 2016 in Becker's Hospital Health IT and CIO Report). Unfortunately, as this article articulates, SRMH's questionable record and reputation on data integrity is already objectively and publicly known.

Conclusion

Granting on-site access to the E.H.R. is reasonable to inspect records that SRMH is already required to maintain. This request does not create an unreasonable burden, nor is the request unreasonably broad in scope.

Respectfully, the Defendant has attempted to mischaracterize duplicate records of Plaintiff or "merging" of Records [32] advocating for it a customary practice [33] rather than acknowledging it as an **error**. SRMH's own E.H.R. vendor Meditech describes duplicate records as an "error" in its training materials (which may be caused by '. miscommunication…,' 'scheduler error,' 'admissions errors" [34] and is designed to prevent among other things "Allergies, adverse reactions, and duplicate orders."[35]

I am not seeking to create an unreasonable burden to SRMH by creating a mirror image of the Defendant's entire system, merely the opportunity to inspect and copy the data associated with **one** patient, the Plaintiff Ms. Gutierrez. Once I am provided with E.H.R. access, the time

required to finding Ms. Gutierrez record should take minutes, if the system is properly configured.

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I swear and affirm under the laws of the United States that the above statements are true and correct to the best of my knowledge and belief. I specially reserve the right to amend add to or subtract from the opinions in this document as new facts or testimony of other experts becomes available to me. The opinions in this document do not necessarily contain the full measure of opinions I may render at trial.

DATED this 20th_ day of July 2018 at Newport Beach, California.

Michael F. Arrigo
Managing Partner,
Healthcare Practice
No World Borders

Citations and Documents Independently Accessed

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[1] June 28, 2018 Page 4 of 5 of Letter Brief by Plaintiff and Defendant.
[2] Id "a blank chart is opened under an "alias" patient name"

[3] Meditech discussion regarding duplicated patient accounts. https://www.meditech.com/prorm/pages/ORcbAS_duplicateaccount.htm

[4] Meditech online brochure regarding "Detect Potential Medication Errors" https://www.meditech.com/productbriefs/pages/product_briefs/bedside_verification.pdf

[5] Duplicate medical records and overlays 101. Imprivata web site. https://www.imprivata.com/intl/duplicate-medical-records-and-overlays-101

[6] Joffe E, Bearden CF, Byrne MJ, Bernstam EV. Duplicate Patient Records – Implication for Missed Laboratory Results. AMIA Annual Symposium Proceedings. 2012;2012:1269-1275.

[7] National Academies Press, To Err Is Human: Building a Safer Health System, published by the Institute of Medicine, 1999. http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf

[8] The Health Information Technology for Economic and Clinical Act (HITECH ACT) enacted as part of the 2009 American Reinvestment and Recovery Act. To date, As of May 2018, more than 545,600 health care providers received payment for participating in the Medicare and Medicaid (PI) Programs. CMS has paid out $38,220,758,479 in incentive funds. Source: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May2018_SummaryReport.pdf

[9] National Academies Press, To Err Is Human: Building a Safer Health System, published by the Institute of Medicine, 1999. http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf

[10] Id

[11] Id

[12] The Health Information Technology for Economic and Clinical Act (HITECH ACT) enacted as part of the 2009 American Reinvestment and Recovery Act. To date, As of May 2018, more than 545,600 health care providers received payment for participating in the Medicare and Medicaid (PI) Programs. CMS has paid out 38,220,758,479 in incentive funds. Source: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May2018_SummaryReport.pdf

[13] Centers for Disease Control, https://www.cdc.gov/ehrmeaningfuluse/introduction.html

[14] https://www.healthit.gov/topic/laws-regulation-and-policy/health-it-legislation

[15] Monitoring National Implementation of HITECH: Status and Key Activity Quarterly Summary. Office of the National Coordinator for Health Information Technology U.S. Department of Health and Human Services Washington, D.C. Prepared by: Mathematica Policy Research Inc 600 Alexander Park Princeton, NJ 08540 https://www.healthit.gov/sites/default/files/globalevaluationquarterlyreport_jan-march2013.pdf

[16] "Using Data Mining to Detect Health Care Fraud and Abuse: A Review of Literature" Hossein Joudaki, Arash Rashidian, Behrouz Minaei-Bidgoli, Mahmood Mahmoodi, Bijan Geraili, Mahdi Nasiri, Mohammad Arab

Glob J Health Sci. 2015 Jan; 7(1): 194–202. Published online 2014 Aug 31.

[17] The $272 billion Swindle," The Economist, May 31, 2014. https://www.economist.com/united-states/2014/05/31/the-272-billion-swindle

[18] Meaningful Use Syndromic Surveillance. CDC. https://www.cdc.gov/ehrmeaningfuluse/Syndromic.html

[19] The NCPDP http://ncpdp.org/Standards-Development/Standards-Information

[20] Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data? https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part2.pdf

[21] Regenstrief Institute is the owner and overall steward of the LOINC vocabulary standard. Led by Clem McDonald, MD, Regenstrief's informaticians initiated the LOINC effort in 1994. Regenstrief serves as the standards development organization (SDO) for LOINC. The LOINC team at Regenstrief maintains the LOINC database and supporting documentation, processes submissions and edits to the content, develops and curates accessory content (descriptions, hierarchies, other attributes, etc), develops the RELMA mapping program, and coordinates LOINC releases. In addition, Regenstrief continues to cultivate the LOINC community worldwide. The LOINC effort at Regenstrief is led by Daniel J. Vreeman, PT, DPT, MS, Director of LOINC and Health Data Standards. To help guide the overall LOINC development, Regenstrief organized the LOINC Committee. LOINC.org https://loinc.org/about/loinc-development/

[22] Field experience with HHS and 15 years implementing EHR software in hospitals and physician practices.

[23] "What is Clinical Decision Support" https://www.healthit.gov/sites/default/files/clinicaldecisionsupport_tipsheet.pdf

[24] Legal EHR Policy Template, Developed by members of the EHR Practice Community, May 2007. http://bok.ahima.org/PdfView?oid=71541

[25] Validating Laboratory Results in Electronic Health Records: A College of American Pathologists Q-Probes Study, National Library of Medicine, National Institute of Health https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5513146/

[26] Meaningful Use Data from CMS Eligible Hospitals

[27] Providence St. Joseph Health website http://www.psjhealth.org/about-us

[28] Medicaid Hospital Incentive Payments Calculations, CMS.gov https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/MLN_TipSheet_MedicaidHospitals.pdf

[29] "I am submitting a claim for Federal Funds, and the use of any false claims, statements, or documents, or the concealment of a material fact used to obtain a Medicare EHR Incentive Program hardship exception, may be prosecuted under applicable Federal or State criminal laws and may also be subject to civil penalties.

" https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/HardshipException_Hospital_Application.pdf

[30] Centers for Medicare and Medicaid, CMS.gov https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/docmatters-ehr-providerfactsheet.pdf

[31] EHR Incentive Programs Supporting Documentation for Audits Last Updated: February 2013 https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHR_SupportingDocumentation_Audits.pdf

[32] June 28, 2018 Page 4 of 5 of Letter Brief by Plaintiff and Defendant.

[33] Id "a blank chart is opened under an "alias" patient name"

[34] Meditech discussion regarding duplicated patient accounts. https://www.meditech.com/prorm/pages/ORcbAS_duplicateaccount.htm

[35] Meditech online brochure regarding "Detect Potential Medication Errors" https://www.meditech.com/productbriefs/pages/product_briefs/bedside_verification.pdf